

CLAIMS

1. A sterile composition comprising a complex of a therapeutic peptide and a polysaccharide selected from the group consisting of cellulose derivatives, chitin, chitosans, galactomannans, and mixtures thereof, wherein said complex has been sterilised with ionising radiation.

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2. A sterile composition according to claim 1, wherein said peptide is selected from the group consisting of growth factors, haemostatic agents, antimicrobial agents, antibacterial agents, anti-adhesion agents and collagen fragments.

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3. A sterile composition according to claim 2, wherein the peptide comprises a growth factor having human mitogenic or angiogenic activity.

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4. A sterile composition according to claim 3, wherein the growth factor is selected from the group consisting of fibroblast growth factor (FGF), Platelet derived growth factor (PDGF), transforming growth factors (TGF- α , TGF- β_1 , TGF- β_2), nerve growth factors (NGF- α , NGF- β), epidermal growth factor (EGF), bone morphogenetic protein, insulin-like growth factors (IGF-I or IGF-II), and mixtures thereof.

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5. A sterile composition according to any preceding claim, wherein said composition further comprises a biopolymer selected from the group consisting of structural proteins, polyanionic polysaccharides, and mixtures thereof.

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6. A sterile composition according to claim 5, wherein said structural proteins are selected from the group consisting of native-collagen types, atelocollagen, pepsin-solubilized collagen, gelatin, fibronectin and laminin.

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7. A sterile composition according to claim 6, wherein said structural proteins consist essentially of native fibrous collagen.

8. A sterile composition according to any preceding claim, wherein said polysaccharide is selected from the group consisting of oxidized celluloses, chitosans, and salts and mixtures thereof.

5 9. A sterile composition according to claim 8, wherein said polysaccharide is selected from the group consisting of ORC and nORC.

10. A sterile composition according to any preceding claim, wherein said composition comprises a mixture of native fibrous collagen, and ORC.

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11. A sterile composition according to any preceding claim, wherein the weight ratio of said therapeutic peptide to said polysaccharide is from 1:10⁶ to 1:10.

15 12. A sterile composition according to claim 11, wherein said weight ratio of from 1 to 10⁵ to 1:100.

13. A sterile composition according to claim 12, wherein said weight ratio is from 1 to 10⁴ to 1:1000.

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14. A sterile composition according to any preceding claim, wherein said composition comprises a freeze-dried or solvent dried sponge.

25 15. A sterile composition according to claim 14, further comprising a free radical scavenger.

16. A sterile composition according to any preceding claim, wherein said composition is a viscous liquid or gel for topical administration to the human or animal body.

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17. A sterile composition according to any one of claims 1 to 15, wherein said composition is a liquid for intravenous administration to the human or animal body.

18. A sterile composition according to any one of claims 1 to 13, wherein said therapeutic peptide and polysaccharide are coated onto a surface of a solid carrier.

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19. A sterile composition according to claim 18, wherein said solid carrier is a woven or nonwoven fabric, a polymer film, or a web, suitable for application to a surface of a wound.

10 20. A sterile composition according to claim 18 or 19, wherein said solid carrier is bioabsorbable.

21. A sterile composition according to claim 20, wherein said solid carrier comprises a woven or nonwoven ORC cloth.

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22. A sterile composition according to any preceding claim which is sterile packaged.

23. A process for the preparation of a sterile therapeutic composition comprising the steps of:

providing a complex of a therapeutic peptide with a polysaccharide; and sterilizing said complex; followed by

dispersing said complex in or on a pharmaceutically acceptable carrier, said polysaccharide being selected from the group consisting of cellulose derivatives, chitin, chitosans, galactomannans, and mixtures thereof.

25 24. A process according to claim 23, wherein said step of providing comprises mixing said therapeutic peptide with said polysaccharide in a solvent, followed by removing said solvent to leave said complex.

25. A process according to claim 24, wherein said solvent is an aqueous solvent.

26. A process according to claim 24 or 25, wherein said solvent is removed by freeze drying or solvent drying.

5 27. A process according to any one of claims 23 to 26 wherein said step of sterilizing is carried out with ionizing radiation or by treatment with a gas plasma.

28. A process according to claim 27, wherein said ionizing radiation is
10 gamma radiation.

29. A process according to any one of claims 23 to 28, wherein said complex comprises less than 4% by weight of water during said step of sterilizing.

15 30. A process according to any one of claims 23 to 29, wherein said step of dispersing is carried out under aseptic conditions, after said step of sterilizing.

31. A process according to any one of claims 23 to 30 for the preparation of a sterile composition according to any one of claims 1 to 22.
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32. A process for the preparation of a sterile therapeutic peptide comprising the steps of:
25 providing a therapeutic peptide;
forming a complex between the therapeutic peptide and a polysaccharide;
sterilizing said complex; followed by
separating the therapeutic peptide from said complex under aseptic conditions to obtain said sterile therapeutic peptide, said polysaccharide being selected from the group consisting of cellulose derivatives, chitin,
30 chitosans, galactomannans, and mixtures thereof.

33. A process according to claim 32, wherein said step of separating comprises extracting the therapeutic peptide from the complex with an aqueous solvent.